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EXAMINER

SISSON, BRADLEY L

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 04/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2004.
 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11-18 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 1-9 and 11-18 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

4) ☐ Interview Summary (PTO-413)

DETAILED ACTION

Withdrawal of Finality

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-5, 7-9, 11, and 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Attention is directed to the decision in *University of Rochester v. G.D. Searle & Co.* 68 USPQ2D 1424 (Fed. Cir. 2004) at 1428:

To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. *Vas-Cath*, 935 F.3d at 1563; see also *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997) (patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention"); *In re Gosteli*, 872 F.2d 1008, 1012 [10 USPQ2d 1614] (Fed. Cir. 1989) ("the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed"). Thus, an applicant complies with the written-description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using

“such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention.” Lockwood, 107 F.3d at 1572.

4. For convenience, claims 1 and 13, the only independent claims, are reproduced below.

1. (previously presented) A pair of oligonucleotide primers, for use as a single primer set in the amplification of a target sequence located within the LTR region of the genome of HIV-1, said primer pair consisting essentially of a first hybridizing oligonucleotide being 10-26 nucleotides in length and comprising at least a fragment of 10 sequential nucleotides of a sequence selected from the group consisting of:

SEQ ID 1: G GGC GCC ACT GCT AGA GA;

SEQ ID 2: G TTC GGG CGC CAC TGC TAG A;

SEQ ID 3: CGG GCG CCA CTG CTA;

and a second hybridizing oligonucleotide being 10-26 nucleotides in length and comprising at least a fragment of 10 sequential nucleotides of a sequence selected from the group consisting of:

SEQ ID 4: CTG CTT AAA GCC TCA ATA AA; and

SEQ ID 5: CTC AAT AAA GCT TGC CTT GA.

13. (previously presented) A pair of oligonucleotide primers consisting of:

(i) a first hybridizing oligonucleotide selected from the group consisting of:

SEQ ID 1: G GGC GCC ACT GCT AGA GA;

SEQ ID 2: G TTC GGG CGC CAC TGC TAG A; [and]

SEQ ID 3: CGG GCG CCA CTG CTA; and

SEQ ID 9: aat tct aat acg act cac tat agg gAG AGG GGC GCC ACT GCT AGA GA; and

(ii) a second hybridizing oligonucleotide selected from the group consisting of:

SEQ ID 4: CTG CTT AAA GCC TCA ATA AA; and

SEQ ID 5: CTC AAT AAA GCT TGC CTT GA.

5. In the response of 10 September 2002, claims 1 and 2 were amended whereby the phrase “consisting of” was broadened to “consisting essentially of.”

VERSION WITH MARKINGS TO SHOW CHANGES MADE

1 (twice amended). A pair of oligonucleotide[s] primers, for use as a single primer set in the amplification of a target sequence located within the LTR region of the genome of HIV-1, said primer pair consisting essentially of a first hybridizing oligonucleotide being 10-[50] 26 nucleotides in length and comprising at least a fragment of 10 sequential nucleotides of a sequence selected from the group consisting of:

SEQ ID 1: G GGC GCC ACT GCT AGA GA;

SEQ ID 2: G TTC GGG CGC CAC TGC TAG A;

SEQ ID 3: CGG GCG CCA CTG CTA;

and a second hybridizing oligonucleotide being 10-[50] 26 nucleotides in length and comprising at least a fragment of 10 sequential nucleotides of a sequence selected from the group consisting of:

SEQ ID 4: CTG CTT AAA GCC TCA ATA AA;

SEQ ID 5: CTC AAT AAA GCT TGC CTT GA;

SEQ ID 12: GAT GCA TGC TCA ATA AAG CTT GCC TGG AGT.

2 (twice amended). A pair of oligonucleotides according to claim 3, consisting essentially of a first oligonucleotide being 10-[50] 26 nucleotides in length and comprising at least a fragment of 10 sequential nucleotides of the sequence:
SEQ ID 1: G GGC GCC ACT GCT AGA GA and a second oligonucleotide being 10-[50] 26 nucleotides in length and comprising at least a fragment of 10 sequential nucleotides of the sequence SEQ ID 5: CTC AAT AAA GCT TGC CTT GA.

Page 2, last paragraph, of the 10 September 2002 response directs attention to page 5, lines 24-28 of the original disclosure as providing support for the amendments. For convenience, said lines are reproduced below.

polymerization. A typical primer contains at least about 10 nucleotides in length of a
25 sequence substantially complementary or homologous to the target sequence, but somewhat longer primers are preferred. Usually primers contain about 15-26 nucleotides but longer primers may also be employed, especially when the primers contain additional sequences such as a promoter sequence for a particular polymerase.

6. For purposes of examination, the phrase "consisting essentially of" has been interpreted

"consisting essentially of" as substantially any length and of any nucleotide composition outside of

the 10 sequential nucleotides found in any of SEQ ID NO: 1-5. While page 6 of the specification describes primers as optionally comprising a promoter sequence, naming T3, T7, and SP6, only SEQ ID NO: 9-11 are found that actually provides a description of a nucleic acid sequence that comprises nucleotides outside of a core sequence, which in this case is SEQ ID NO: 1-3, and then the added sequence is only that of the T7 promoter.

7. While the specification does provide a description of core sequences, e.g., 10 consecutive nucleotides from specified SEQ ID Nos., the specification does not, however, provide an adequate written description of the virtually limitless flanking sequences. As noted above, "the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing" (emphasis added). Absent this full, clear, concise, and exact description and absent convincing evidence to the contrary, claims 1-5, 7-9, 11, and 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-3 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,474,796 (Brennan).

10. For purposes of examination, the claims 1-3 and 8 have been interpreted as encompassing oligonucleotides that are either free or bound to a support.

11. Brennan, column 9, discloses preparing oligonucleotides that "represent every possible permutation of the 10-mer oligonucleotide." By default, the preparation of every possible 10-mer oligonucleotide would comprise every 10-mer oligonucleotide claimed presently.

Accordingly, claims 1-3 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,474,796 (Brennan).

Declaration under 37 CFR 1.131

12. The declaration filed on 18 February 2004 under 37 CFR 1.131 is sufficient to overcome the US Patent 6,001,558 (Backus et al.) reference.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

— (a) The contents of the prior art

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 1-9, 11-14, 16, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,221,610 (Montagnier et al.) in view of US Patent 5,474,796 (Brennan), US Patent 5,576,176 (Adams et al.), and Research Genetics.

17. Montagnier et al., column 19, third paragraph, bridging to column 20, disclose primers for detecting HIV-1 and methods of doing same. At column 19, last paragraph, bridging to column 20, first two lines, Montagnier et al., teach explicitly of directing primers to conserved regions and specifically teaches that one such region of conserved sequences is found in the long terminal repeat, or LTR. It is noted that the LTR is the very region from which applicant has selected the instantly claimed primers/probes; see the response of 26 December 2000, page 7, lines 13-15, wherein is stated:

The primers of the present invention are not from the GAG region, but instead are from the long terminal repeat (LTR) of HIV-1."

18. It is abundantly clear that Montagnier et al., are directing the public to this very region for the selection of primers and probes. Furthermore, they provide motivation in selecting sequences that allow for the detection of multiple isolates when they teach that the LTR is “highly conserved.” Accordingly, it is clear that the nucleotide sequence of HIV, and especially the LTR region was known and had been characterized to the point that it was known to be highly conserved and was also highly prized as a tool in detecting HIV in a sample.

19. Montagnier et al., column 20, second full paragraph, states that by using PCR, which they consider to be more sensitive, one would be able to eliminate viral-isolation assays.

20. Montagnier et al., column 19, teach explicitly that the amplification product can range from 10-300 nucleotides. It is noted that the amplification product produced by the claimed primers falls within this size range.

21. Montagnier et al., also teach using probes to detect the amplification product where the probes are complementary to the amplification product.

22. On their own, the teachings of Montagnier et al., render obvious any primer pair that can be used to amplify HIV LTR sequences, where the amplification product ranges in size from 10 to 300 nucleotides. Said disclosures are also considered to render obvious any probe that would be used to detect any of said amplification products.

23. Brennan teaches explicitly of developing and using every claimed oligonucleotide that is 10 nucleotides in length (see above rejection of claims 1-3 and 8 under 35 USC 102(b)).

24. Brennan does not teach developing oligonucleotides of a greater length.

25. Adams et al., column 7, discloses primers that used to detect and monitor HIV in patients. As seen in said column 7, the disclosed “Primer 3,” which is 21 nucleotides in length, fairly

encompasses at least 10 nucleotides of each of applicants' primers/probes represented by SEQ ID NO: 1; SEQ ID NO.: 2; and SEQ ID NO: 3.

26. Research Genetics, through their advertisement, disclose for sale software that allows the ordinary artisan to set parameters whereby the software will automatically screen all possible nucleotide sequence comparisons and provide a listing of those primers that meet the established criteria. As seen in the publication, such parameters to be employed in the selection of primer and probe sequences include desired specificity, length, GC content, secondary structure characteristics, etc. Accordingly, the designing of a sequence over that of another, especially when the very source is known and the prior art directs one to use such a sequence, speaks of routine optimization. It is well settled that routine optimization is not patentable, even if it results in significant improvements over the prior art. In support of this position, attention is directed to the decision in *In re Aller, Lacey, and Hall*, 105 USPQ 233 (CCPA 1955):

Normally, it is to be expected that a change in temperature, or in concentration, or in both, would be an unpatentable modification. Under some circumstances, however, changes such as these may impart patentability to a process if the particular ranges claimed produce a new and unexpected result which is different in kind and not merely in degree from the results of the prior art. *In re Dreyfus*, 22 C.C.P.A. (Patents) 830, 73 F.2d 931, 24 USPQ 52; *In re Waite et al.*, 35 C.C.P.A. (Patents) 1117, 168 F.2d 104, 77 USPQ 586. Such ranges are termed "critical" ranges, and the applicant has the burden of proving such criticality. *In re Swenson et al.*, 30 C.C.P.A. (Patents) 809, 132 F.2d 1020, 56 USPQ 372; *In re Scherl*, 33 C.C.P.A. (Patents) 1193, 156 F.2d 72, 70 USPQ 204. However, even though applicant's modification results in great improvement and utility over the prior art, it may still not be patentable if the modification was within the capabilities of one skilled in the art. *In re Sola*, 22 C.C.P.A. (Patents) 1313, 77 F.2d 627, 25 USPQ 433; *In re Normann et al.*, 32 C.C.P.A. (Patents) 1248, 150 F.2d 708, 66 USPQ 308; *In re Irmscher*, 32 C.C.P.A. (Patents) 1259, 150 F.2d 705, 66 USPQ 314. More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Swain et al.*, 33 C.C.P.A. (Patents) 1250, 156 F.2d 239, 70 USPQ 412; *Minnesota Mining and Mfg. Co. v. Coe*, 69 App. D.C. 217, 99 F.2d 986, 38 USPQ 213; *Allen et al. v. Coe*, 77 App. D. C. 324, 135 F.2d 11, 57 USPQ 136. (Emphasis added)

27. In view of the foregoing remarks as to the teachings of the prior art of record, it would have been obvious to one of ordinary skill in the art at the time the instantly claimed invention was made to have used the sequences of Brennan and optionally the commercially-available "Designer PCR" computer program of Research Genetics so to arrive at the claimed oligonucleotides. As presented above, Brennan clearly teaches every claimed 10-mer oligonucleotide, and Adams et al., teach oligonucleotides that comprise applicant's SEQ ID Nos. 1-5. With the prior art teaching a variety of primers that could be used to amplify one strand, and with the prior art teaching the desired range of amplification products, the selection of a corresponding second primer so to yield an amplification product that ranges from 10-300 bases would have been obvious to the ordinary artisan, for as is clearly evident, the starting material, direction, guidance and motivation are all present in the art.

28. With the public being armed with the sequences, preferred size ranges, every 10-mer claimed and software that will perform the necessary calculations and produce nucleotide sequences that meet such criteria, the selection of primer sequences that have such features would have been profoundly obvious. And given the art-recognized sensitivity of PCR and the interests that abounds in HIV-related diagnostics, the ordinary artisan would have been highly motivated as well. Additionally, said ordinary artisan would have been motivated to have configured the primer pair(s) in a kit format as such would have been an obvious commercial expedience, requiring little if any additional research and development.

29. As shown above, the selection of target sequences within the LTR of HIV is taught in the prior art as well as the selection and use of probes that hybridize to the amplification product. Accordingly, with the amplification product taught by the art, and the explicit teaching by

Montagnier et al., to make and use probes that hybridize to amplicons derived from HIV LTR, the probes corresponding to applicant's SEQ ID NO: 6-8 are also obvious.

30. Accordingly, and in the absence of convincing evidence to the contrary, claims 1-5, 7-9, 11-14, 16, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,221,610 (Montagnier et al.) in view of US Patent 5,474,796 (Brennan), US Patent 6,001,558 (Backus et al.), and Research Genetics.

31. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,221,610 (Montagnier et al.) in view of US Patent 5,474,796 (Brennan), US Patent 6,001,558 (Backus et al.), and Research Genetics as applied to claims 1-5, 7-9, 11-14, 16, and 18 above, and further in view of US Patent 5,770,428 (Boris-Lawrie) and US Patent 5,712,385 (McDonough et al.).

32. See above for the basis of the rejection as I relates to the disclosures of Montagnier et al., Brennan, Adams et al., and Research Genetics.

33. While Montagnier et al., teach using probes that hybridize to the amplicons from HIV LTR, neither Montagnier et al., Brennan, Backus et al., nor Genetic Research teach explicitly of an oligonucleotide comprising applicants SEQ ID NO: 6-8.

34. Boris-Lawrie, column 11 discloses in their SEQ ID NO: 5 an HIV oligonucleotide that comprises applicant's SEQ ID NO: 7 and 8.

35. Boris-Lawrie does not teach of applicant's SEQ ID NO: 6.

36. McDonough et al., at columns 5 and 29, disclose their SEQ ID NO: 49, which comprises applicant's SEQ ID NO: 6.

37. The disclosures of Boris-Lawrie and McDonough et al., whether taken collectively or individually meet a limitation of claim 6.

38. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have further modified the above-identified method of Montagnier et al., Brennan, Adams et al., and Research Genetics with the disclosures of Boris-Lawrie and/or McDonough et al., as Boris-Lawrie and McDonough both teach oligonucleotide sequences that could be used in the identification of HIV sequences. As presented above, the prior art clearly teaches the need and desire to develop oligonucleotide sequences that are useful in the detection of HIV, the causative agent of AIDS. The cited prior art also clearly teaches that the starting sequence was known to those of skill in the art and that attention has been directed to the LTR region, and that the prior art goes even further and teaches specifically oligonucleotide sequences that can be used to detect HIV-specific sequences. In view of the demonstrated need, the detailed teachings and readily available means to select suitable variants ("Designer PCR" computer program), the ordinary artisan would have been both amply motivated and would have had a reasonable expectation of success.

39. For the above reasons, and in the absence of convincing evidence to the contrary, claim 6 is rejected under 35 USC 103(a) as being unpatentable over US Patent 5,221,610 (Montagnier et al.) in view of US Patent 5,474,796 (Brennan), US Patent 5,576,176 (Adams et al.), and Research Genetics as applied to claims 1-9, 11-14, 16, and 18 above, and further in view of US Patent 5,770,428 (Boris-Lawrie) and US Patent 5,712,385 (McDonough et al.).

40. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,221,610 (Montagnier et al.) in view of US Patent 5,474,796 (Brennan), US Patent 5,576,176 (Adams et al.), and Research Genetics as applied to claims 1-9, 11-14, 16, and 18 above, and further in view of Zaaijer et al.

41. For convenience, claim 15 is reproduced below.

15. (previously presented) The pair of oligonucleotide primers of claim 13, wherein said first hybridizing oligonucleotide is SEQ ID 9: aat tct aat acg act cac tat agg gAG AGG GGC GCC ACT GCT AGA GA and wherein said second hybridizing oligonucleotide is SEQ ID 5: CTC AAT AAA GCT TGC CTT GA.

42. Attention is directed to page 7, lines 13-16, of the disclosure which reads:

the sequences of SEQ ID 1-3 are operably linked to a promoter sequence (the T7 promoter sequence). This makes the sequences especially suitable for use as upstream primer in a transcription based amplification technique such as NASBA.

43. See above for the basis of the rejection as it pertains to the disclosure of Montagnier et al., Brennan, Adams et al., and Research Genetics. It is noted with particularity that Adams et al., disclose a primer for amplifying HIV that comprises nucleotides corresponding to applicant's SEQ ID NO: 1

44. Neither Montagnier et al., Brennan, Adams et al., or Research Genetics disclose using primers that comprise a T7 RNA polymerase region.

45. Zaaijer et al., page 178, disclose a method of detecting HIV by isothermal amplification, or NASBA. As seen therein, the method comprises using a primer that comprises a T7 RNA polymerase recognition site.

46. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated a T7 RNA polymerase recognition sequence in a primer used for NASBA-based detection of HIV, (Zaaijer et al.) into a primer corresponding to SEQ ID NO: 1, as the prior art fairly teaches development and use of SEQ ID NO: 1, as well as its use in the amplification of HIV sequences. It would have also been obvious to have combined such a primer with a primer corresponding to SEQ ID NO: 5 as Montagnier et al., teaches selection of primer pairs that result in an amplicon of from 10 to 300 nucleotides in length, a length that encompasses the amplicon resulting from the use of SEQ ID NO: 9 and SEQ ID NO: 5.

47. Therefore, and in the absence of convincing evidence to the contrary, claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,221,610 (Montagnier et al.) in view of US Patent 5,474,796 (Brennan), US Patent 5,576,176 (Adams et al.), and Research Genetics as applied to claims 1-9, 11-14, 16, and 18 above, and further in view of Zaaijer et al.

Conclusion

48. Rejections and/or objections that appeared in the prior Office action and which have not been repeated hereinabove have been withdrawn.

49. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

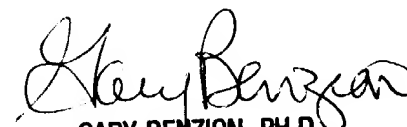
50. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
21 April 2004



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4/23/04